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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,552	11/21/2003	Are Bogšnes	5432.220-US	3561

23650 7590 07/11/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,552

Applicant(s)

BOGSNES, ARE

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/290,856.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/21/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by Thim *et al.* (EP 0195691, September 1986).

Thim *et al.* disclose human insulin precursors of the formula B-X-Y-A, wherein X and Y are each lysine or arginine, are expressed in yeast with an expression vehicle capable of expressing a DNA-sequence encoding the human insulin precursor (page 9, line 15-page 14, line 5). The human insulin precursor is recovered from the culture medium, purified by column chromatography such as RP-18, anti-insulin Sepharose column and preparative HPLC (Examples 6 and 7; Fig 8A; claims 1 and 2), characterized by amino acid sequence analysis (Example 8),

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and converted into human insulin by enzymatic treatment (Examples 10-12). Since the claims recite “comprises” in the term “said composition comprises about 0.02% to 0.2% glycosylated insulin or insulin analogue”, thus the claim can read as a composition comprising recombinant insulin with a percentage of glycosylated insulin greater than 0.2%. The claim also reads a composition containing recombinant insulin without any glycosylated insulin because of the term “about 0.02% to 0.2% glycosylated insulin or insulin analogue”.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as anticipated by Kjeidsen *et al.* (U. S. Patent 6,214,547, filed January 23, 1998).

Kjeidsen *et al.* teach a polypeptide such as proinsulin is produced in high yield using a synthetic prepro-leader peptide lacking N-linked glycosylation, with no or limited O-linked glycosylation to confer secretion competence, and to improve the recovery of polypeptide in yeast (column 3, lines 1-65). Introduction of a suitable enzyme cleavage site between the prepro-leader and the heterologous protein, and expression in a Kex2 endoprotease negative *S. cerevisiae* strain followed by RP-HPLC purification and *in vitro* maturation gives a peak of des(B30) human insulin (MW 5706; column 9, line 56-column 10, line 61; Example; Fig. 5 and 6). The des(B30) human insulin, which is not glycosylated, anticipates claims 1 and 2 since the claim recites the term “said composition comprises about 0.02% to 0.2% glycosylated insulin or insulin analogue”, which reads the composition containing insulin or an analog thereof with 0% of glycosylated insulin or insulin analogue.

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Conclusion

3. No claims are allowed.

Art of Record

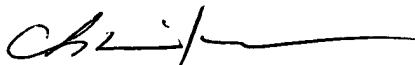
Dubaquic *et al.* (US 2002/0160955 A1) teach the amino acid sequences of human proinsulin and insulin (Fig. 4). Both the pro-peptide and mature peptide indicates N- and O-glycosylation sites.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

July 8, 2005